

### REMARKS

Applicant's Attorney extends his appreciation for the telephone interview between Examiner Jastrzab and Applicant's attorney Juettner on March 12, 2003.

In the previous Amendment A, claims 16-18, 23, 25, 27, 29 and 30 were cancelled without prejudice. In this Amendment B, claims 2, 4, 8-11, 13-14, 21-22, 26, 28, 36-37 and 40-41 have been cancelled without prejudice.

The remaining claims have been extensively amended to distinguish over the newly cited references, namely, U.S. Pat. No. 4,552,552 to *Polaschegg et al.* and U.S. Pat. No. 6,464,476 to *Ross et al.*, in a sincere effort to place the application in condition for allowance. Reconsideration is respectfully requested.

Independent Claim 1 (Twice Amended) contains the subject matter of claims 1, 2, 8 and 9. It is submitted that the references do not disclose the pumping cycle defined in the claim. In particular the '552 reference discloses a pumping cycle that is the reverse of that of claim 1. In claim 1 the bladder expands/contracts progressively in the direction of flow, whereas in the '552 reference the bladder expands/contracts progressively opposite the direction of flow.

Independent Claim 7 (Twice Amended) combines the subject matter of claims 1, 2 and 7. The references do not teach a pump where the bladder and bladder driving fluid are a unitary body of semisolid material.

Independent Claim 31 (Amended) calls for a majority of the surface area of the *pumping system* to expand/contract and thereby change surface area. This feature is not disclosed in the cited references.

Independent Claim 32 (Amended) calls for the bladder wall to be thinner at the inlet and thicker at the outlet, which is the opposite of that disclosed in the '552 reference.

Independent claims 33-34 were previously indicated to be allowable.

Independent claim 35 (Amended) has been amended to change the word "blood" to --fluid-- in the preamble. It is allowable because the references do not disclose a fluid pressure regulator in the space between the bladder and housing for selectively expanding/contracting selective areas of the bladder.

Independent claims 38 is allowable because the references do not disclose expressly or inherently reducing the formation of blood clots by changing the surface area of the inner surface of the bladder. It is submitted that the references showing dialysis pumps would not inherently perform this method step because it is well known that Heparin and other anticoagulants were routinely used to prevent blood coagulation in dialysis systems. See attached articles, J.T. Daugirdas and T.S. Ing, *Handbook of Dialysis*, pp. 87-97; A.R. Nissenson, R.N. Fine and D.E. Gentile, *Clinical Dialysis* (1990) pp. 161-167; P.W. Saunders, H. Taylor and J.J. Curtis, *Hemodialysis Without Anticoagulation* (1985) pp. 32-35; and U.S. Patent No. 3,811,800 to Shill, col. 4, lines 28-42. These references all

indicate that blood clotting is a problem in dialysis. The standard or conventional solution in the art is to add Heparin, a well known anticoagulant. In cases where the patient is at risk of bleeding and cannot receive a normal dose of Heparin, the conventional solution is to (a) delay dialysis, if that is not possible, (b) administer a low dose of Heparin, or if that is not possible (c) proceed with no anticoagulant and risk blood clot formation in the dialysis system. See e.g., *Clinical Dialysis* at page 166. The references do not suggest expanding/contracting the interior surface areas of the systems to reduce clot formation.

Viewing the art as a whole, the dialysis system of the '552 reference would operate with application of Heparin as routinely taught in the art at the time. The presence of Heparin would prevent coagulation of the blood before it reached the pump. The expansion/contraction of the liner 66 would not, therefore, inherently reduce the formation of blood clots.

Independent Claim 42 (Amended) combines the subject matter of claims 1 and 42, presented in independent form. The claim is allowable because the references do not disclose a bladder comprised of a plurality of different materials.

Dependent claims 43-46 are newly presented.

All the remaining claims are dependent from one of the above discussed independent claims and are allowable for the same reasons and for the combinations recited in those claims.

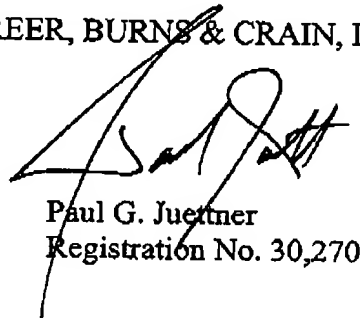
It is respectfully submitted that pending claims 1, 3, 5-7, 12, 15, 19-20, 24, 31-35, 38-39 and 42-46 are allowable over the cited references. Early issuance of a Notice of Allowance is earnestly solicited.

Applicant's undersigned attorney believes that a telephone interview may be useful to facilitate an effective examination of the remaining claims, and respectfully requests to be contacted by telephone at the Examiner's early convenience.

Respectfully submitted,

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By



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**"Version with Markings to Show Changes Made"**

**In the Claims:**

1. (TWICE AMENDED) A fluid pump comprising:

an elastic bladder, at least a portion of the interior surface area of said bladder being changeable between a contracted state have a first surface area and an expanded state having a second surface area that is substantially greater than said first surface area, said bladder having a fluid inlet and a fluid outlet;

~~means for alternately expanding and contracting said bladder to change the interior surface area and volume of said bladder; and~~

means for causing substantially one-way fluid flow through said bladder;

a housing around at least a portion of said bladder, an annular volume being defined in the space between said housing and said bladder, said annular volume being occupied by a driving fluid;

means for changing the pressure of said driving fluid in said annular volume to alternately expand and contract said bladder to change the interior surface area and volume of said bladder; and

a fluid flow regulating means in said annular volume between said bladder and said housing for expanding and contracting selected areas of said bladder adapted, in a filling phase, to expand a selected area of said bladder adjacent said inlet and thereafter progressively expand the remaining areas of said bladder towards said bladder outlet, and during an ejection phase, to initially contract said bladder adjacent said bladder inlet and

thereafter progressively contract the remaining areas of the bladder towards said bladder outlet.

7. (TWICE AMENDED) A fluid pump ~~as in claim 2~~ comprising, an elastic bladder, at least a portion of the interior surface area of said bladder being changeable between a contracted state having a first surface area and an expanded state having a second surface area that is substantially greater than said first surface area, said bladder having a fluid inlet and a fluid outlet;

\_\_\_\_\_ a housing around at least a portion of said bladder and defining a space between said housing and said bladder for receiving a bladder actuating fluid;

\_\_\_\_\_ means for alternately increasing and decreasing the pressure of said actuating fluid for alternately expanding and contracting said bladder to change the interior surface area and volume of said bladder;

\_\_\_\_\_ means for causing substantially one-way fluid flow through said bladder;  
and

\_\_\_\_\_ wherein said bladder and said actuating fluid are a unitary body of semisolid material, the surface of said semisolid material functioning as said bladder interior surface.

24. (TWICE AMENDED) A blood pump as in claim 3~~5~~15, further comprising at least one extensible strut spanning the interior of said bladder.

31. (AMENDED) A method of pumping blood in the circulatory system of a human in need thereof comprising the steps of

(a) providing a blood pumping system having an extensible and contractible bladder, said pumping system having an inlet and an outlet;

(b) connecting the inlet and outlet of ~~the bladder~~said pumping system to the human's circulatory system;

(c) expanding a majority of the interior surface area of ~~the bladder~~said pumping system by at least a few percent, ~~including and~~ expanding the volume of the bladder to draw blood into the bladder through the inlet;

(d) contracting a majority of the interior surface area of said blood pumping system ~~the bladder~~ by at least a few percent, ~~including and~~ contracting the volume of the bladder to pump blood out of the outlet of ~~the bladder~~said system; and

(e) rhythmically repeating steps (c) and (d).

32. (AMENDED) A fluid pump comprising:

a bladder, at least a portion of the interior surface area of said bladder being changeable, said bladder having a fluid inlet and a fluid outlet, said bladder having thickness variations for controlling the expansion and contraction of said bladder, said bladder have a thinner wall thickness at said inlet and a thicker wall thickness at said outlet;

means for alternately expanding and contracting said bladder to change the interior surface area and volume of said bladder; and

means for causing substantially one-way fluid flow through said bladder.

35. (AMENDED) A ~~bleed~~-fluid pump comprising:

a housing;

an extensible and contractible bladder in said housing, a space defined between said housing and said bladder for receiving a bladder driving fluid, said bladder having an inlet and an outlet;

a check valve to at least one of said bladder inlet and outlet;

means for altering the pressure of the driving fluid to alternately expand and contract the interior surface area and volume of said bladder to define a pumping cycle, most of said interior surface area of said bladder adapted to expand and contract with each said pumping cycle; and



a fluid pressure regulator in said space to selectively control the rate of expansion or contraction of selected areas of said bladder.

42. (AMENDED) A fluid pump ~~as defined by claim 1~~ comprising:  
a bladder, at least a portion of the interior surface area of said bladder being  
changeable, said bladder having a fluid inlet and a fluid outlet;  
\_\_\_\_\_ means for alternately expanding and contracting the bladder to change the  
interior surface area and volume of said bladder;  
\_\_\_\_\_ means for causing substantially one-way fluid flow through said bladder;  
and  
\_\_\_\_\_ wherein said bladder is comprised of a plurality of different materials to  
control the rate of expansion or contraction of selected areas of said bladder.

43. (NEW) A method of for reducing the formation of blood clots during blood pumping as in claim 38, wherein step of changing the interior surface area of said bladder includes changing a majority of the interior surface area of said pump.

44. (NEW) A method of for reducing the formation of blood clots during blood pumping as in claim 38, wherein said stretching step is a filling phase comprising expanding a selected area of said bladder adjacent said inlet and thereafter progressively

expanding the remaining areas of said bladder towards said bladder outlet; and said contracting step is an ejection phase, comprising initially contracting said bladder adjacent said inlet and thereafter progressively contracting the remaining areas of said bladder towards said outlet.

45. (NEW) A method of for reducing the formation of blood clots during blood pumping as in claim 38, wherein said bladder is has a curved configuration representative of a natural heart with said inlet being adjacent said outlet, and wherein said steps of elastically expanding and contracting said bladder comprises milking the blood through said bladder in a smooth flow substantially free from areas of turbulence and areas of stagnation.

46. (NEW) A fluid pump as in claim 35 for pumping blood, wherein said bladder is has a curved configuration representative of a natural heart with said inlet being adjacent said outlet.

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PATENT APPLICATION

U.S. PATENT AND TRADEMARK OFFICE  
CERTIFICATION OF FACSIMILE TRANSMISSION

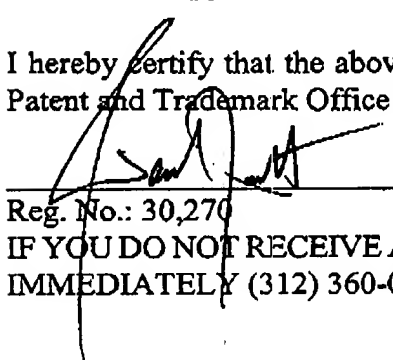
TO: Examiner Jastrzab, J. )  
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FACSIMILE NO.: (703) 746-7027 )  
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In re Application of: )  
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For: BLOOD PUMP )  
)  
Art Unit: 3762 )  
)  
Examiner: Jeffrey Jastrzab )

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Description: **Enclosed is a Amendment Transmittal, Amendment B, Attached Journal Articles and Patent which was filed on March 12, 2003 for the above-referenced application. (Examiner Jeffrey Jastrzab, please call me if you have any questions or need additional information)**

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